

Appln No.: 09/678,357  
Amendment Dated: October 24, 2006  
Reply to Office Action of April 24, 2006

#### REMARKS

This is in response to the Official Action mailed April 24, 2006 for the above-captioned application. Reconsideration and allowance of the application are respectfully urged.

Applicants request an extension of time sufficient to make this paper timely, and enclose the fee.

Claim 14 has been amended in view of the Examiner's objection to change the extra period to a comma. Claims 18 and 19 have been canceled without prejudice rendering the objection to and the § 112, first paragraph rejection of these claims moot.

The Examiner rejected all of the pending claims under 35 USC § 112, second paragraph, citing a variety of reasons. Applicants respectfully remind the Examiner that the burden rests with the Examiner to do more than just state that some phrase is indefinite. Rather, "it is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to determine the scope of protection defined by the claim when read in light of the specification." *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (POBAI 1989). The Examiner has not met this burden here.

The Examiner states that the preamble of claim 14 that refers to diagnosing the possible presence of gastritis is inconsistent with the closing that certain results are indicative of gastritis and therefore that claim 14 is indefinite. Applicants respectfully disagree. The method is performed on individuals that may have gastritis, but certainly there is no requirement or expectation that it will only be performed on individuals that will yield a positive test result. Thus, the preamble defines the patient population. The closing refers to interpretation of results, that is when a test result indicate gastritis. There is no inconsistency and a person skilled in the art would have no difficulty understanding the scope of the claim.

The Examiner states that the final passage is indefinite because "it is not clear what applicants intend in the recitation of the above phrase." Applicants do not understand what the Examiner's issue is. As indicated above, this phrase provides the standard by which the object of the preamble, diagnosis of gastritis, is achieved. The Examiner has not explained why this would not be understood by the person skilled in the art.

The Examiner has also made multiple rejections based on the absence of antecedent basis. While the standard for compliance with § 112, second paragraph says nothing about formulaic rules such as antecedent basis, only about clarity, Applicants have amended claim 14 to consistently refer to "concentration" rather than "level" throughout the claims.

Appln No.: 09/678,357  
Amendment Dated: October 24, 2006  
Reply to Office Action of April 24, 2006

With respect to claim 21, the phrase "antrum, or pangastritis" has been amended to "antrum gastritis or pangastritis" in view of the Examiner's remarks. Thus, this limitations the location of the gastritis.

The Examiner also rejected the pending claims under 35 USC § 103 as obvious over Lindgren in view of newly cited Lin et al. The Examiner also rejected the claims as obvious over the previous cited combination of Oksanen and Ma further in view of Lin. Applicants respectfully traverse these rejections, and submit that the references do not give rise to a *prima facie* suggestion of the presently claimed invention.

The references in this case all disclose a variety of individual assays for testing for gastritis. What the previously cited references do not disclose, however is the step of multiplying the concentration of pepsinogen I by the concentration of *Helicobacter pylori* antibodies to get a number, and comparing the number to a number calculated similarly for the normal population. As characterized by the Examiner, "Lin et al teach multiplying value of pepsinogen I by the level of gastrin and develop a scoring system." He therefore argues that at the time the invention was made it would have been obvious to use the scoring system of Lin with the markers of the other references, and to multiply pepsinogen I times *H. pylori* antibody concentrations. There is no suggestion of this in the references and therefore no case for an obviousness rejection.

Lin multiplies two numbers as part of the scoring system disclosed there. These numbers are pepsinogen and gastrin levels. These are **not the same two numbers** that are multiplied in the present claims. Thus, the Examiner is in effect arguing that, because two particular parameters can be multiplied to result in meaningful information, multiplication of any and all pairs of test results (including the pair recited in Applicants claims) becomes obvious. The Examiner has clearly not provided any reasoning to support such a supposition, nor any reasons to pick the particular pair of test results that are recited as multiplied in the present claims. It is not apparent from or suggested by the teaching of Lin et al that the concentration of pepsinogen I can **also** be multiplied by the concentration of *H. pylori* antibodies to identify and characterize patients with gastritis.

Furthermore, while the primary references all deal with gastritis, the Lin reference relates to testing for gastric adenocarcinoma (cancer). The Examiner has not provided any connection between these references, and specifically has not indicated why a test that is intended for diagnosis of cancer would be considered by a person skilled in the art as having any relevance to the detection of gastritis. Accordingly, even if Lin taught exactly the same test as presently claimed there would be no motivation to combine the references relied upon, and no *prima facie* case of obviousness.

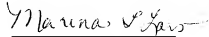
Appln No.: 09/678,357

Amendment Dated: October 24, 2006

Reply to Office Action of April 24, 2006

In view of the foregoing, Applicants submit that this application is in form for allowance.  
Favorable reconsideration and allowance of all claims are respectfully urged.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Marina T. Larson".

Marina T. Larson Ph.D.

PTO Reg. No. 32,038

Attorney for Applicant

(970) 262 1800